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LATHAM, SAEEDA MONEE				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/596,621

Applicant(s)

OH, YOUN-JEONG

Examiner

Saeeda Latham

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/DP)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____
- Paper No(s)/Mail Date: 6/19/2006, 6/27/2006

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: The claim uses improper claim language. Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation, 37 CFR 1.75(i). See MPEP § 608.01(m).

2. The claim should read the following way:

A method for producing a *Phellinus linteus* beverage comprising

adding 0.07-0.2 weight parts *Phellinus linteus* into 100 weight parts of R/O water with 20-30 hardness;

boiling the R/O water containing *Phellinus linteus* for a required time to obtain *Phellinus linteus* extract;

filtering the *Phellinus linteus* extract;

producing a *Phellinus linteus* beverage by mixing the *Phellinus linteus* extract and R/O water at fixed ratio; and

sterilizing the beverage by UHT method at 121°C - 130°C for 90 seconds.

The claim should include lower case letters (as in words "adding," "boiling", etc) and should be indented to indicate different steps. The weight part ranges need the symbol "-" or the word "to" to indicate a range.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The term "20-30 hardness" in claim 1 is a relative term which renders the claim indefinite. There is no indication of units for water hardness (e.g. parts per million, grains per gallon). The term "20-30 hardness" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For examination purposes, the hardness concentration is in ppm.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horiuchi JP 2002-262820 in view of Sakai et al., USPGpub 2004/0161524 in further**

view of Lee et al., USPN 6645383 in further view of Kitahora et al., USPN 6076334 in further view of Smith (article, Introduction to Food Process Engineering).

8. Claims 1-3 relate to a method of producing a *Phellinus Linteus* beverage.

Horiuchi teaches the method of efficiently extracting active ingredients from mushroom [0004]. Mushrooms with a high content of beta-glucan include *Phellinus Linteus* which has an antitumor activity, immunity enhancing activity, and antihyperglycaemic action [0008, 0012]. Water is added to the particles of ground mushroom [0016]. The quantity of water is 4-40 times the dry weight of mushroom [0023]. Hot water extraction is done by boiling for 30 minutes to 2 hours wherein most water-soluble active ingredients are extracted. After hot water extraction, liquid separation is done using a microfilter [0023]. The condensed extract can be made into a health drink [0027].

9. Horiuchi does not teach weight parts. According to applicant, the ratio of water to *Phellinus linteus* is 100 weight parts to 0.07-0.2 weight parts, indicating that 1 liter of water contains 0.7-2 g of *Phellinus linteus* [considered the ratio of *Phellinus linteus* to water is 0.0007 to 0.002] (Page 3, [32]). Sakai teaches the process for producing a liquid plant extract containing plant powder wherein the content of active ingredients is higher than that in the plant itself and is added to a drink. The plants include *Phellinus linteus* [0056, Page 4, column 2]. The solvent used for the extraction may be water such as distilled water, deionized or pure water [0064, 0065]. For the extraction, solvent may be used in an amount of 0.1 to 10,000 parts by weight based on 1 part by weight of the plant (considered the ratio of *Phellinus linteus* to water is 0.0001 to 10) [0073]. The liquid plant extract or plant powder can be added to dairy beverages, soft drinks, juice

[0108]. It would have been obvious to one having ordinary skill in the art, at the time of the invention, to have selected 0.0007 to 0.002 as the ratio of *Phellinus linteus* to water as Sakai's overlapping range to produce the beverage of Horiuchi with high content of active ingredients from *Phellinus linteus* extract.

10. Neither Horiuchi nor Sakai teaches R/O water or water hardness. Lee teaches a process for the treatment of feed typically tap water through a primary membrane (abstract). The process involves purification that produces water modified to improve its taste characteristics (column 1, lines 10-17). Reverse osmosis (RO) of water excludes most ions (column 1, lines 45-48). Reverse osmosis is used to purify water to produce drinkable or potable water (column 2, lines 11-13). The method involves improving the taste of RO water by a post-filtration blending method (column 2, lines 25-27). The range of acceptable water hardness by varying the reverse osmosis units and nanofiltration units has an upper limit of 100ppm, wherein hardness of concentration of at least 20ppm produced superior product water (see Example 1). It would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized drinkable or potable water that has been purified by reverse osmosis by selecting a hardness concentration of 20-30 ppm as Lee's range to make the extract and beverage of Horiuchi with enhanced taste and flavor.

11. Horiuchi, Sakai, nor Lee teach the UHT method or filling in containers. Kitahora teaches plastic containers such as PET bottles are widely used for packaging beverages such as coffee drinks, teas, colas or juices. When a beverage is filled in these plastic containers, such beverages are sterilized in accordance with UHT

sterilization treatment, are filled in the sterilized plastic container, and the containers are sealed with sterilized caps (column 1, lines 10-17). PET is used a container material that is molded wherein the interior is inherently in a state of being heat sterilized (column 2, lines 26-29). It would have been obvious to one having ordinary skill in the art at the time of the invention to have sterilized a beverage by UHT, filled PET bottles, and sealed them as Kitahora to produce the beverage of Horiuchi that would be easily manufactured and properly sterilized for consumers.

12. Horiuchi, Sakai, Lee nor Kitahora teach the temperature of sterilization. Smith teaches UHT processing in which temperatures up to 140°C are used for periods of the order of 2-4 seconds to achieve commercial sterility of a continuous flow liquid. The sterile product is then placed into pre-sterilised packaging which give superior organoleptic properties and greater retention of nutrients (see Principles). It would have been obvious to one having ordinary skill in the art at the time of the invention to have known how to modify conditions during the course of routine experimentation and optimization procedures by selecting a temperature of 121 to 130°C based on Smith's range under a longer treatment time to produce the product of Horiuchi that is a completely sterile beverage.

13. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong et al., WO99/27802 in view of Lee et al., USPN 6645383 in further view of Kitahora et al., USPN 6076334 in further view of Smith (article, Introduction to Food Process Engineering).

14. Claims 1-3 relate to a method of producing a *Phellinus Linteus* beverage. Hong teaches a health beverage containing the extract of *Phellinus linteus* as the main ingredient and manufacturing of a beverage that can reduce the incidence rate of cancers (abstract). 1-5000mg of the extract can be added to 100mL beverage that is sterilized, if necessary (Page 4, lines 6-11). Mycelia was obtained from the *Phellinus linteus* culture and extracted in Example 1. 100g mycelia and 500mL distilled water was boiled, the extracted water layer was collected (Page 6, lines 2-7). Beverages were obtained from adding the extract to beverage ingredients (see Preparation Examples 1-11). One embodiment, 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 100 mg of extract of *Phellinus linteus* was diluted with purified water, sugar and filled in each bottle of 100mL and sealed. Each mixture was sterilized in a conventional preparation method of cola to prepare each cola (see Preparation Example 3).

15. Hong does not teach weight parts. According to applicant, the ratio of water to *Phellinus linteus* is 100 weight parts to 0.07-0.2 weight parts, indicating that 1 liter of water contains 0.7-2 g of *Phellinus linteus* (Page 3, [32]). Hong teaches 1-5000mg of the extract can be added to 100mL beverage that is sterilized, if necessary (Page 4, lines 6-11). It would have been obvious to one having ordinary skill in the art, at the time of the invention, to have selected the ratio of water to *Phellinus linteus* is 100 weight parts to 0.07-0.2 weight parts which would have been 7mg to 200 mg extract in 100ml beverage (considered the water content) because of the overlapping range.

16. Hong does not teach R/O water or water hardness. Lee teaches a process for the treatment of feed typically tap water through a primary membrane (abstract). The

process involves purification that produces water modified to improve its taste characteristics (column 1, lines 10-17). Reverse osmosis (RO) of water excludes most ions (column 1, lines 45-48). Reverse osmosis is used to purify water to produce drinkable or potable water (column 2, lines 11-13). The method involves improving the taste of RO water by a post-filtration blending method (column 2, lines 25-27). The range of acceptable water hardness by varying the reverse osmosis units and nanofiltration units has an upper limit of 100ppm, wherein hardness of concentration of at least 20ppm produced superior product water (see Example 1). It would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized drinkable or potable water that has been purified by reverse osmosis with a hardness concentration of 20-30ppm as Lee's range to make the extract and beverage of Hong with enhanced taste and flavor.

17. Neither Hong nor Lee teaches the UHT method. Kitahora teaches plastic containers such as PET bottles are widely used for packaging beverages such as coffee drinks, teas, colas or juices. When a beverage is filled in these plastic containers, such beverages are sterilized in accordance with UHT sterilization treatment, are filled in the sterilized plastic container, and the containers are sealed with sterilized caps (column 1, lines 10-17). PET is used a container material that is molded wherein the interior is inherently in a state of being heat sterilized (column 2, lines 26-29). It would have been obvious to one having ordinary skill in the art at the time of the invention to have sterilized a beverage by UHT, filled PET bottles, and sealed them as Kitahora to

produce the beverage of Hong that would be easily manufactured and properly sterilized for consumers.

18. Hong, Lee nor Kitahora teach the temperature of sterilization. Smith teaches UHT processing in which temperatures up to 140°C are used for periods of the order of 2-4 seconds to achieve commercial sterility a continuous flow liquid. The sterile product is then placed into pre-sterilised packaging which give superior organoleptic properties and greater retention of nutrients (see Principles). It would have been obvious to one having ordinary skill in the art at the time of the invention to have known how to modify conditions during the course of routine experimentation and optimization procedures by selecting a temperature of 121 to 130°C based on Smith's range under a longer treatment time to produce the product of Hong that is a completely sterile beverage.

Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Saeeda Latham whose telephone number is 571-270-1154. The examiner can normally be reached on Monday to Thursday 8:00AM - 5:00PM EST.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on 571-272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. L./
Examiner, Art Unit 1794

/Rena L. Dye/
Supervisory Patent Examiner, Art Unit 1794